K032827

DEC - 8 2003

EXHIBIT # 7

510(k) Summary

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rules dated December 14, 1994, this summary is submitted by:

The Kendall Company
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: August 4, 2003

1. Contact Person

Gail Christie
Manager, Regulatory Affairs
(508) 261-8440

2. Name of Medical Device

Classification Name: Empty Container for the collection and processing of blood and blood components.

Common or Usual Name: Kit, Umbilical Cord Blood Collection

3. Identification of Legally Marketed Device

The proposed Kendall LifeTrace Umbilical Blood Collection Kit is substantially equivalent in intended use, design, and function to the DeRoyal Surgical, Umbilicup 510(k) No. K02753.

4. Device Description

The Kendall LifeTrace Umbilical Blood Collection Device consists of a cup shaped body, divided in half. The top half is used to collect umbilical cord blood for analysis and has a lid. The bottom half contains an Angel Wing Transfer device that is used to puncture the rubber stoppers of vacuum tubes. The device is used to facilitate the transfer of the collected blood from the top chamber to the tube.

5. Device Intended Use

The device is intended for single use only. The device is used for umbilical cord blood sampling and transfer.

6. Product Comparison

The proposed device has the same technological characteristics as the predicate devices. The proposed Kendall LifeTrace Umbilical Blood Collection Kit is substantially equivalent to the predicate devices in the following areas:

- Each product is single use.
- Each product consists of an empty cup with an attached needle assembly accessible to a blood collection tube.
- Each product is used to collect and transfer umbilical cord blood

7. Nonclinical Testing

Biocompatibility testing of the proposed device has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 8 2003

Ms. Gail Christie
Manager, Scientific Services/Regulatory Affairs
Tyco Healthcare
15 Hampshire Street
Mansfield, MA 02048

Re: k032827
Trade/Device Name: Kendall LIFETRACE Umbilical Blood Collection Kit
Regulation Number: 21 CFR 864. 9100
Regulation Name: Empty container for the collection and processing of blood and blood components
Regulatory Class: Class II
Product Code: KSR
Dated: September 4, 2003
Received: September 10, 2003

Dear Ms. Christie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K032827

Device Name: Kendall LIFETRACE Umbilical Blood Collection Kit

Indications for Use:

The device is used for umbilical cord blood sampling and transfer. The device is intended for single use only.

Please Do Not Write Below This Line – Continue On Another Page If Needed

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032827